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Dated: December 28, 2007 Signature: /Jeanne M. Brashear/56,301
(Jeanne M. Brashear)

Docket No.: 13024/38627A
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
McMichael et al.

Application No.: 10/624,328 Confirmation No.: 6971

Filed: July 22, 2003 Art Unit: 1614

For: Method of Treatment for Psychological Conditions by Administration of Nerve Growth Factor Examiner: Alicia R. Hughes

REPLY BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This reply brief is submitted to respond to points of argument and to correct erroneous statements made in the Examiner's Answer dated November 1, 2007, to Appellants' Appeal Brief. This Reply Brief is filed within two-months of the mailing of the Examiner's Answer. Accordingly, this Reply Brief is timely filed.

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is Milkhaus Laboratory, Inc.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 20 claims pending in application.

B. Current Status of Claims

1. Claims canceled: 3, 6-7, 19
2. Claims withdrawn from consideration but not canceled: None
3. Claims pending: 1, 2, 4, 5, 8-18 and 20-24
4. Claims allowed: None
5. Claims rejected: 1, 2, 4, 5, 8-18 and 20-24

C. Claims On Appeal

The claims on appeal are claims 1, 2, 4, 5, 8-18 and 20-24.

IV. STATUS OF AMENDMENTS

No amendments to the application were made after the Final Rejection dated January 22, 2007. All previous amendments have been entered and are reflected in the pending claims, set forth in Appendix A.

V. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1, 2, 4, 5, 8-18 and 20-24 are unpatentable under 35 U.S.C. § 103(a) over Frey II (U.S. Patent Application Publication No. 2003/0072793) in view of Beers (The Merck Manual of Diagnosis and Therapy, 17th Edition, pp 1525-1539 and pp 1932-1933, 1999).

B. Whether claims 1, 2, 4, 5, 8-18 and 20-24 are unpatentable under 35 U.S.C. § 103(a) over Siuciak (U.S. Patent No. 5,599,560) in view of Beers (The Merck Manual of Diagnosis and Therapy, 17th Edition, pp 1525-1539 and pp 1932-1933, 1999).

VI. ARGUMENT (REPLY TO EXAMINER'S ANSWER)

A. The rejection of claims 1, 2, 4, 5, 8-18 and 20-24 under 35 U.S.C. § 103(a) as being unpatentable over Frey II in view of Beers should be reversed because Frey II is directed to a particular mode of administration and not to the use of any particular compound for the treatment of any particular disorder.

Frey II is not directed to the administration of any particular compound for the treatment of any particular condition; rather, it is directed to a specific mode of administration of a plurality of potentially therapeutic compounds to the central nervous system (CNS) of a subject by way of a tissue innervated by the trigeminal nerve that is outside of the nasal cavity. Frey II lists more than forty (40) possible therapeutic agents that can be administered by its method and also lists more than seventeen (17) conditions or disorders for which its mode of administration may be useful[1].

Frey II simply does not disclose or suggest the administration of NGF for the treatment of affective disorders as asserted by the Examiner. The Examiner improperly characterizes Frey II in the Examiner's Answer as teaching the use of "'preferred neurologic agents,' namely growth factors such as nerve growth factor...in the treatment of affective and anxiety disorders." However, Frey II discloses more than twenty-five (25) "preferred neurologic agents" for use in its mode of administration and does not correlate the use of any one of the "preferred neurologic agents" for the treatment of any specific condition or disorder! See paragraphs [0051] and [0169] of Frey II. In fact, Frey II provides absolutely no direction for the selection of a specific neurologic agent for use in the treatment of any specific condition or disorder! Because Frey II fails to specifically correlate any particular neurologic agent as a therapeutic for any specific condition or disorder, one of skill in the art would not know which of the many neurologic agents disclosed in Frey II could be used for the treatment of, for example, affective disorders. It is only in hindsight that a reference teaching a specific mode of administration (and a plurality of agents that could be administered by the specific mode of administration) for the potential treatment of a plurality of conditions or disorders, could be construed as teaching a method of treatment for a specific disorder by administering one of the many agents disclosed in the reference.

[1] In fact, Frey II at paragraph 169 states "The present method can be employed to deliver agents to the brain for diagnosis, treatment or prevention of disorders, diseases of the CNS, brain and/or spinal cord." (Emphasis added.)

B. The rejection of claims 1, 2, 4, 5, 8-18 and 20-24 under 35 U.S.C. § 103(a) as being unpatentable over Siuciak in view of Beers should be reversed because Siuciak simply does not teach the use of NGF for the treatment of any disorder. In fact, Siuciak makes no mention of NGF at all!

It is improper for the Examiner to conclude that because Siuciak teaches the use of NT-3, NT-4 and BDNF for the treatment of depression that is also teaches the use of a different protein with different biological activities (i.e., NGF) for the treatment of psychological disorders. Appellants provided evidence[2] during the prosecution of this application which refutes the Examiner's apparent assertion that all neurotrophins have the same biological activity and can be used interchangeably and in fact teaches away from the utility of NGF for the treatment of the recited psychological conditions normally treated with NT-3, NT-4 or BDNF. The Examiner did not dispute or even acknowledge the disparate activities of the members of the neurotrophin family in the Examiner's Answer.

Contrary to the Examiner's assertions in the Answer, the Appellants' specification neither states that NGF is the same protein as other members of the neurotrophin family nor equates the activity of NGF with that of the other members of the neurotrophin family. The Examiner mischaracterizes a sentence in the Appellants' specification at page 12, lines 27-28, in order to support the rejection.

> "NGF, a prototypical neurotrophic factor and member of the neurotrophin family, promotes a wide range of responses in target cells."
> (Specification, page 12, lines 27-28).

The "prototypical" nature of NGF referred to in the Appellants' specification is that NGF, as well as other members of the neurotrophin family, promotes a wide range of responses in target cells. The Examiner apparently asserts that because Appellants' specification states NGF as being a "prototypical neurotrophic factor," NGF has the same activities as other neurotrophic factors. However, as discussed above, Appellants have submitted evidence[3] refuting these alleged teachings. Finally, Appellants have never argued "that NGF illustrates the typical qualities of neurotrophic factors and members of the

[2] In response to the Final Office Action mailed January 22, 2007, Appellants submitted Friedman et al., (Exp. Neph., 119:72-78, 1999), which reports that NGF exhibits a different biological activity than NT-3, NT-4 and BDNF. Friedman et al. was also provided in the Appellants' Appeal Brief as Exhibit C.
[3] Friedman et al., supra.

neurotrophin family" as asserted by the Examiner at page 10 of the Examiner's Answer. Instead, Appellants have consistently argued that NGF is a different protein with different biological activities than the specific neurotrophic factors disclosed in Siuciak (i.e., BDNF, NT-3 and NT-4) and have introduced evidence as to why NGF would not be expected to have utility in treating the recited psychological conditions normally treated with NT-3, NT-4 or BDNF.

C. Conclusion

Neither Frey II nor Siuciak disclose or suggest that NGF can be used to successfully treat psychological conditions. While it is now known that NGF can be used to alleviate the symptoms a psychological condition, there was no teaching in Frey II, Siuciak or any other art relied upon by the Examiner that one would be successful in doing so prior to Appellants' disclosure. The only motivation or suggestion to use NGF to alleviate the symptoms of a psychological disorder arises out of the Appellants' specification and it is impermissible to use the Appellants' own disclosure to find a motivation for the claimed invention, as this would be the epitome of hindsight reconstruction.

In view of the foregoing, Appellants respectfully request that the Examiner's final rejections of claims 1, 2, 4, 5, 8-18 and 20-24 be reversed.

Dated: December 28, 2007

Respectfully submitted,

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 10/624,328

1. (Previously presented) A method of alleviating symptoms of a psychological condition selected from the group consisting of depression, anxiety disorders, panic attacks, premenstrual dysphoric disorder (PMDD), and premenstrual syndrome (PMS) comprising administering to a subject in need thereof nerve growth factor in an amount effective to treat one or more symptoms of said psychological condition.

2. (Original) The method of claim 1, wherein said psychological condition is depression.

3. (Canceled)

4. (Original) The method of claim 1, wherein said psychological condition is an anxiety disorder.

5. (Original) The method of claim 1, wherein said psychological condition is panic attacks.

6-7. (Canceled)

8. (Original) The method of claim 1, wherein said psychological condition is premenstrual dysphoric disorder (PMDD).

9. (Original) The method of claim 1, wherein said psychological condition is premenstrual syndrome (PMS).

10. (Original) The method of claim 1, wherein said nerve growth factor is administered by a mode selected from the group consisting of sublingual, bucal, oral drench, subcutaneous, intradermal, or intravenous.

11. (Original) The method of claim 10, wherein said nerve growth factor is administered sublingually.

12. (Original) The method of claim 1, wherein said nerve growth factor is administered at a daily dosage of/from 0.001 to 1 microgram per day.

13. (Original) The method of claim 1, wherein said nerve growth factor is administered at a daily dosage of from 0.01 to 0.1 microgram per day.

14. (Previously presented) The method of claim 1, wherein the symptoms are selected from a group consisting of sleep disorders, tension headaches, cold sweats, and constipation.

15. (Previously presented) A method of alleviating symptoms of a psychological condition selected from the group consisting of sleep disorders, tension headaches, and constipation comprising administering to a patient in need thereof nerve growth factor in an amount effective to treat one or more said symptoms.

16. (Original) The method of claim 15, wherein said symptom is a sleep disorder.

17. (Original) The method of claim 15, wherein said symptom is a tension headache.

18. (Original) The method of claim 15, wherein said symptom is constipation.

19. (Canceled)

20. (Original) The method of claim 15, wherein said nerve growth factor is administered by a mode selected from the group consisting of sublingual, bucal, oral drench, subcutaneous, intradermal, or intravenous.

21. (Original) The method of claim 20, wherein said nerve growth factor is administered sublingually.

22. (Original) The method of claim 15, wherein said nerve growth factor is administered at a daily dosage of/from 0.001 to 10 micrograms per day.

23. (Original) The method of claim 15, wherein said nerve growth factor is administered at a daily dosage of/from 0.05 to 1 micrograms per day.

24. (Original) The method of claim 15, wherein said nerve growth factor is administered at a daily dosage of/from 0.01 to 0.1 micrograms per day.

25-28. (Canceled)